AWARD NUMBER: W81XWH-19-1-0827

TITLE: Evaluating the Impact of Prosthetic Device Features on the Experience of Prosthesis Use

PRINCIPAL INVESTIGATOR: Emily Graczyk, PhD

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PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

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Evaluating the Impact of Prosthetic Device Features on the Experience of Prosthesis Use

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5d. PROJECT NUMBER
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5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Cleveland VA Medical Research and Education Foundation
10701 East Blvd, Cleveland, OH 44106

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

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12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Our goal is to understand the critical factors associated with outcome acceptance following upper limb loss. We aim to develop a unified theoretical model that describes the psychosocial experience of upper limb prosthesis use and predicts outcome acceptance following upper limb loss. This conceptual framework will enable clinicians and researchers to evaluate and predict patient outcomes following limb loss, and to design interventions that improve outcomes. The specific aims are: 1) Assess the impact of the experience of prosthesis dexterity and control on outcome acceptance, 2) Assess the impact of sensory feedback experience on outcome acceptance, and 3) Refine the theoretical model derived from qualitative analyses by exploring the quantitative relationships between aspects of the model of outcome acceptance. The qualitative analyses will yield a theoretical model of outcome acceptance that includes psychosocial factors and prosthetic device factors related to dexterity, control, and sensory feedback. We hypothesize that experiences of prosthesis dexterity, control, and sensory feedback will both directly influence and modulate psychosocial factors of prosthesis use and user attitudes. We hypothesize that quantitative data collected through survey research will triangulate findings from the qualitative analyses, confirm the directionality of the conceptual relationships, and predict the relative weightings of relationships. During this year, we have hired new personnel to support the study and trained all study staff. We have developed interview guides, recruitment materials, screening processes, and qualitative analysis processes for the qualitative components of the study. We have submitted regulatory documents and received approval from the Central VA IRB. We have conducted mock interviews and developed an initial code set based on an analysis of this mock data. We have initiated relationships with partners at Hanger Clinic, Richmond VA Medical Center, and the Amputee Coalition for assistance with participant recruitment. We have developed a preliminary set of measures for the quantitative portion of the study and created data management systems and processes to store and analyze this data.

15. SUBJECT TERMS

Prosthesis; Outcome acceptance; Mixed methods; Upper limb loss; Amputee; Qualitative research; Interview; Survey

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC
Unclassified	Unclassified	Unclassified	Unclassified	18	19b. TELEPHONE NUMBER *(include area code)*

TABLE OF CONTENTS

1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

Our goal is to understand the critical factors associated with outcome acceptance following upper limb loss. We aim to develop a unified theoretical model that describes the psychosocial experience of upper limb prosthesis use and predicts outcome acceptance following upper limb loss. This conceptual framework will enable clinicians and researchers to evaluate and predict patient outcomes following limb loss, and to design interventions that improve outcomes. The proposed two-year study is a mixed methods (qualitative and quantitative) study using an observational design. The qualitative component of the study will involve data collection through telephone interviews with 18 participants and analyses using a grounded theory approach with constant comparison methods. The quantitative component involves administration of standardized measures quantifying constructs of the theoretical model in 120 participants and analyses to produce a structural equation model of outcome acceptance. Participants will include persons with unilateral acquired upper limb loss at the trans radial or trans humeral level who use currently available prosthetic devices.

2. **KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

Prosthesis; Outcome Acceptance; Qualitative research; Mixed methods; Upper limb loss; Amputee; Interview; Survey

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?
List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Specific Aims 1 and 2	Timeline	Completion
Major Task 1: Obtain regulatory approvals	Months	**80%**
Prepare regulatory documents and research protocol	1-2	12/5/19
Finalize consent form and human subjects' protocol	1-2	11/15/19
Finalize participant interview guide	1-2	12/10/19
Coordinate with Sites for IRB protocol submission	1-2	12/6/19
Submit amendments, adverse events, and protocol deviations as needed	As needed	N/A
Milestone Achieved: Local IRB Approval	3	
Milestone Achieved: HRPO Approval	4	
Major Task 2: Coordinate study staff and prepare for study		**95%**
Advertise for, interview, and hire study coordinator	1-5	6/8/2020
Purchase study-related equipment and supplies	1-2	2/10/2020

Training of all study staff at Cleveland site visit	4-6	12/10/19
Milestone Achieved: Research staff trained	4-6	12/10/19
Facilitate and coordinate with Sites for training, supervision, and quality checks as needed	4-24	50%
Milestone Achieved: Staff training and study quality maintained	4-24	50%
Major Task 3: Participant recruitment and data collection		**10%**
Develop recruitment fliers for distribution at recruiting partner institutions and advertisement for Amputee Coalition e-blast	1-3	2/15/2020
Begin subject recruitment	5-16	0%
Milestone Achieved: 1st participant consented and enrolled	5-16	
Participants interviewed via telephone, 45-60 min session for each (N=36)	5-16	0%
Milestone Achieved: Report preliminary findings from interviews	11-13	
Major Task 4: Qualitative analysis of interview data		**5%**
Participant interview audio recordings transcribed	5-17	5%
Data analysts analyze transcripts and develop initial codes (open coding)	5-17	10%
Weekly conference calls between Sites for discussion of categories, codes, and iterations on coding process	5-19	10%
Milestone Achieved: Concept categories and codes finalized	11-13	
Determine relationships between categories and directionality of relationships (axial coding)	11-14	0%
Identify the central theme of the research (selective coding)	11-14	0%
Auditing of coding decisions and analysis process	5-16	5%
Milestone Achieved: Theoretical model of outcome acceptance constructed from qualitative analysis	12-15	
Prepare manuscripts and presentations on qualitative analysis and theoretical model	14-17	0%
Milestone Achieved: Report results of qualitative study	14-17	
Specific Aim 3		
Major Task 5: Prepare research protocol for Specific Aim 3		**0%**
Refine research protocol based on the findings of the interview study (Aims 1 and 2)	11-13	0%
Finalize set of survey metrics to measure important concepts identified in the theoretical model	11-13	0%
Amend IRB protocol with final survey set	11-13	0%
Milestone Achieved: Protocol for survey study finalized and approved by local IRB and HRPO	11-13	
Major Task 6: Survey data collection		**0%**
Recruit participants for survey study	11-22	0%
Surveys delivered via telephone to participants (N=120)	11-22	0%
Milestone Achieved: Report findings from surveys	18-22	
Major Task 7: Data analysis		**0%**
Perform statistical analyses of survey data with assistance of statistical consultant	20-24	0%

Perform structural equation modeling of survey results	20-24	0%
Milestone Achieved: Theoretical model refined with quantitative data	20-24	
Perform all analyses, share output and findings with all investigators	18-24	0%
Prepare manuscripts and presentations to disseminate findings of full study	18-24	0%
Milestone Achieved: Report results from study	22-24	

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

1. Major Activities:

Our major activities this quarter included obtaining VA central IRB approval on August 6th, 2020 and submitting documents for individual local approvals for the Providence and Cleveland sites. Our new study coordinator has continued to acclimate to the coordinator role and has been trained on practices associated with the study. We have submitted formal research collaboration applications and recruitment documents to both the Amputee Coalition & Hanger Prosthetics and have been informed that these documents have been received. This process is required for these partners to assist with referral of potential participants. Amputee Coalition is expected to contact the study team within the next week to continue the process. We anticipate recruiting and screening subjects within the next month, followed by conducting interviews shortly after. We have fully prepared for participant engagement and have purchased the visa gift cards to be mailed as participant payment.

2. Specific Objectives:

Our objectives over the past year included:

1. Hire study coordinator (Cleveland site) and research assistant (Providence site)
2. Finalize recruitment and screening documents
3. Develop interview guides for Aims 1 and 2
4. Prepare for and hold kick-off meeting in Cleveland, OH
5. Prepare and submit regulatory documents to central VA IRB
6. Address questions from central VA IRB
7. Prepare and submit regulatory documents for local VA IRB
8. Submit IRB documents to HRPO
9. Purchase audio recorders for data collection
10. Establish team workflow for data collection and management
11. Conduct mock interviews using interview guides and transcribe data
12. Develop initial code set and definitions
13. Code mock interview data with initial code set
14. Submit regulatory documents for local VA R&D
15. Initiate formal research applications with Hanger Clinic and the Amputee Coalition

16. Hire and train Study Coordinator
17. Establish templates and data bases for data collection and management
18. Refine initial code set and definitions

3. Key Outcomes

Throughout this year, the team has made considerable strides to achieve study milestones despite the challenges associated with the COVID-19 pandemic. During the months of September through December 2019, the study team prepared materials including the IRB documents, research protocol, recruitment materials, and informed consent forms. The team investigated the most efficient options for multi-site IRB options, and chose to pre-submit to the central VA IRB on 12/6/19. We connected with clinical and research collaborators to discuss recruitment assistance. The team identified collaborating organizations including the Amputee Coalition and the Richmond VAMC. The Cleveland and Providence sites met biweekly and developed screening procedures for participants as well as finalized the interview guides for Aims 1 and 2. The team successfully conducted the kick-off meeting in Cleveland, OH on December 9th and 10,th 2019. In addition, the Providence site successfully hired a new research assistant, Mrs. Debra Kelty, an experienced qualitative researcher.

In the months of January through March, the team focused on developing and refining the qualitative analysis process. This process involved conducting mock interviews with research colleagues using our interview guides, transcribing the data, establishing team roles and procedures for data management, developing our initial code set, and coding our mock data with that code set. The mock interviews served as a chance for the interviewer to practice, and an opportunity to evaluate the content, wording, and flow of each interview. Afterwards, the mock data was used to assess the process of using the chosen VA approved, HIPAA-complaint professional transcription service, Transcript Outsourcing, LLC., as well as allowed the team to develop our initial code set and code definitions, through the process of open coding. We purchased audio recorders for data collection, and successfully utilized the technology while conducting our mock interviews. We have established a process of securely sending audio files to the transcription service so that the process will be seamless once we begin data collection. The screening script, which establishes eligibility of interested candidates, was created, along with a consent script to collect informed consent via telephone. The study was formally submitted to the VA Central IRB on 2/10/2020. We also continued our search for a study coordinator for the Cleveland site.

During the March- June 2020 quarter, our major activities focused on continuing to develop our qualitative analysis process and train our newly hired study coordinator. A REDCap database was constructed to capture and share the data between Providence and Cleveland. The screening script and all proposed potential surveys for use in Aim 3 were implemented in REDCap. The team continued the central VA IRB review process and prepared documents for the local Cleveland VA IRB. The study team sent emails to our recruiting partners, Hanger Prosthetics and OrthoCarolina, to notify them of impending approval. Finally, we hired a study coordinator, Alesia Lambert, who started the position on June 8th, 2020. During this quarter, her time was dedicated to training, including human subject's protection, hospital and laboratory policies, orientation to the protocol and regulatory process, and types of prosthetics. In addition, we conducted a third mock interview with the lead interviewer and a research colleague. Technical difficulties with the recording equipment during this interview led to the development of a protocol for the set-up and implementation of the recording hardware to prevent future loss of data. We have also worked through the process of transferring the audio files to the external transcription service. A template was created for future transcribed interviews for consistency and ease of coding. A Data Use

Agreement (DUA) was created between the Cleveland VAMC and Transcription Outsourcing LLC. The team developed a case summary template to capture key information about each participant in the interview study. These case summaries will provide a quick view of important information for each participant to expedite theme generation across participants and groups.

In the fourth quarter, we continued to progress in spite of the unique challenges resulting from the COVID-19 pandemic. We obtained central VA IRB approval for the parent study on August 6th, 2020. Due to constraints in the VA Central IRB as a result of COVID-19, we were informed that the approval process had been much slower than usual. We submitted the regulatory documents to the local VA sites and HRPO, and anticipate local site approval within this next quarter. Our new study coordinator has continued to acclimate to the coordinator role and has been trained on recruitment and screening processes. Once we receive local site and HRPO approvals, our study coordinator is ready to begin participant recruitment, screening, and consenting processes. Our study coordinator will also attend the virtual Society of Clinical Research Associates (SOCRA) conference from September 23rd through the 26th in order to develop a greater knowledge base of current information, tools, best practices, and training in research management to assure up-to-date and compliant clinical research practices while engaging with potential participants. We have submitted formal applications and documents to both the Amputee Coalition & Hanger Prosthetics and have been informed that they have been received. Amputee Coalition is expected to contact the study team within the next week to continue the process. This will be a crucial step in the initiation of the recruitment process. We anticipate recruiting and screening subjects within the next month, followed by conducting interviews shortly after. We have fully prepared for participant engagement and have purchased the visa gift cards to be mailed as participant payment.

4. Accomplishments

The study received VA central IRB approval on August 6th, 2020.

What opportunities for training and professional development has the project provided?

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Our study coordinator will attend the virtual SOCRA conference from September 23rd through the 26,th 2020 in order to develop a greater knowledge base of current information, tools, best practices, and training in research management to assure up-to-date and compliant clinical research practices while engaging with potential participants.

The PI and Research Assistant attended several scientific conferences related to neurorehabilitation and prosthetics for professional development and networking. Emily Graczyk and Melissa Schmitt attended the American Orthotics and Prosthetics Association National Assembly in San Diego, CA from September 25th through 28th, 2019. While there, Melissa Schmitt gave a poster presentation and Emily Graczyk gave a symposium presentation about other projects related to prosthetics. Emily Graczyk also attended the Society for Neuroscience annual conference in Chicago, IL from October 19th through 23rd, 2019. She presented a poster on a related project pertaining to prosthetics.

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

We identified a partner to help us attain our recruitment goals for Veterans in this study. Dr. Joseph Webster, who is located at the Richmond VAMC and is the national medical director of the VA Amputee System of Care, agreed to assist with recruitment for our study. This partnership will also provide an opportunity to inform Veterans about the results of the study, once available.

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

During the next reporting period, we anticipate the screening and recruitment of potential participants for the interview portion of the study. Once the interviews are conducted, we will use the coding set and definitions we developed this year to analyze the data. This analysis will enable us to find common themes and concepts in the data to generate a conceptual framework for understanding prosthesis outcome acceptance. Once we have conducted several interviews, we will identify reoccurring concepts that are of interest to measure during the quantitative component of the study (Aim 3). We will then select a definitive set of surveys and questionnaires to target those concepts and amend our IRB and HRPO protocols with this updated set of measures. We will continue holding weekly meetings between the Cleveland and Providence sites to discuss data collection and analysis processes.

4. **IMPACT:** D*escribe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to report.

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to report.

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to report.

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to report.

5. CHANGES/PROBLEMS: *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

Changes in approach and reasons for change

Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Nothing to report.

Actual or anticipated problems or delays and actions or plans to resolve them

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Due to the COVID-19 pandemic, all non-essential, in-person human subjects research processes were halted for the Cleveland and Providence sites. Due to these unforeseen circumstances, the process for hiring a Cleveland site study coordinator took considerably longer than originally anticipated. However, we did successfully onboard a new coordinator in June 2020. The COVID-19 pandemic has resulted in considerable delays in the regulatory approval process, and we still do not have full approvals to begin participant recruitment and enrollment. The process for obtaining approval has been delayed due the slowed responses from the Central VA IRB. Although we submitted our documents in February 2020 and answered all questions promptly, we did not receive Central VA IRB approval until August 2020. We then submitted all regulatory documents to the local IRB and HRPO, but have not yet received approval. Once we receive all IRB and HRPO approvals for our study, we can begin recruitment because our study is conducted via telephone and does not require in person contact or travel. In addition, we may have difficulty recruiting participants during the pandemic because of interruptions to potential participants' normal routines, work, and healthcare visits. In addition, all study personnel are currently working remotely which has ultimately resulted in slower communication. However, we have continued work on the study and have maintained communication through weekly virtual meetings. While our sites are beginning to resume in-person operation, we anticipate that our team will continue to work partially or entirely remotely for the foreseeable future to reduce health risk.

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Due to the COVID-19 pandemic, the team members have been adjusting to unusual working conditions associated with working remotely but have continued to adjust accordingly. The team continues to prepare for full study approval and participant recruitment through refining the interview guides, discussing survey content, and continuing to develop qualitative analysis procedures. However, due to the slower responses from regulatory bodies, we are significantly delayed in beginning participant recruitment and data collection. We anticipate that we will request an extension of the study period to enable us to meet our scientific goals.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Nothing to report.

Significant changes in use or care of vertebrate animals

Nothing to report.

Significant changes in use of biohazards and/or select agents

Nothing to report.

6. **PRODUCTS:** *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

  Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report.

  Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report.

  Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to report.

- **Website(s) or other Internet site(s)**
  List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to report.

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to report.

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to report.

- **Other Products**
  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:
  - *data or databases;*
  - *physical collections;*
  - *audio or video products;*
  - *software;*
  - *models;*
  - *educational aids or curricula;*
  - *instruments or equipment;*
  - *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
  - *clinical interventions;*
  - *new business creation; and*
  - *other.*

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Example:

Name: *Mary Smith*
Project Role: *Graduate Student*
Researcher Identifier (e.g. ORCID ID): *1234567*
Nearest person month worked: *5*

Contribution to Project: *Ms. Smith has performed work in the area of combined error-control and constrained coding.*
Funding Support: *The Ford Foundation (Complete only if the funding support is provided from other than this award.)*

Name:	Emily Graczyk
Project Role:	Principal Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0003-1467-8616
Nearest person month worked:	3
Contribution to Project:	Managed the team, led hiring process for study coordinator, developed interview guides, developed code set and definitions, developed qualitative analysis process, coded mock interview data, trained new coordinator

Name:	Melissa Schmitt
Project Role:	Research Assistant
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	4
Contribution to Project:	Interfaced with IRB and R&D committees, developed interview guides, developed REDCap database, conducted mock interviews, developed code set and definitions, coded mock interview data, trained new coordinator, assisted with case study template development

Name:	Alesia Lambert
Project Role:	Study Coordinator
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	3
Contribution to Project:	Completed research credentialing process at Cleveland VA, trained on study procedures and goals, trained on IRB and regulatory processes, trained on prosthetics types, trained on screening and recruitment procedures, submitted materials to collaborating recruitment partners including Amputee Coalition and Hanger Prosthetics

Name:	Linda Resnik
Project Role:	Site-PI of Providence Site
Researcher Identifier (e.g. ORCID ID):	0000-0002-0168-6759
Nearest person month worked:	1
Contribution to Project:	Managed Providence team, advised on interview guide and code structure refinement, developed qualitative analysis process, coded mock interview data, advised on case study template development

Name:	Debra Kelty
Project Role:	Research Assistant
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	2
Contribution to Project:	Developed qualitative analysis procedures, developed data management workflow, transcribed mock interview data, coded mock interview data, developed case summary template

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to Report.

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:
<u>Organization Name:</u>
<u>Location of Organization: (if foreign location list country)</u>
<u>Partner's contribution to the project</u> (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Organization Name: Amputee Coalition
Location of Organization: 900 East Hill Avenue, Suite 390, Knoxville, TN 37915
Contribution to Project: Collaboration in recruitment of participants

Organization Name: Richmond VA Medical Center
Location of Organization: 1201 Broad Rock Blvd, Richmond VA 23249
Contribution to Project: Collaboration in recruitment of participants

Organization Name: Hanger Prosthetics
Location of Organization: 10910 Domain Drive, Suite 300, Austin , TX 78758
Contribution to Project: Collaboration in recruitment of participants

Organization Name: OrthoCarolina
Location of Organization: 1915 Randolph Rd, Charlotte, NC 28207
Contribution to Project: Collaboration in recruitment of participants

Organization Name: Providence VA Medical Center
Location of Organization: 830 Chalkstone Ave, Providence, RI 02908
Contribution to Project: Collaboration

Organization Name: Case Western Reserve University
Location of Organization: 10900 Euclid Ave, Cleveland, OH 44106
Contribution to Project: In-kind support; Facilities

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

9. QUAD CHARTS:

10. APPENDICES: